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10/092,083	03/06/2002	David McCallister	214240	8537

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EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/092,083

**Applicant(s)**

MCCALLISTER ET AL.

**Examiner**

Shaojia A Jiang

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 December 2003.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 44-52 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 44-52 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This Office Action is a response to Applicant's amendment and response filed on December 16, 2003 wherein claims 1-31 and 32-43 are cancelled; claims 44-52 are newly submitted.

Currently, claims 44-52 are pending in this application.

Claims 44-52 are examined on the merits herein.

### ***Election/Restrictions***

Applicant's affirmation of the telephonic election of the invention of Group II claims 32-43, submitted December 16, 2003 is acknowledged.

Applicant's declarations of Marshall A. Hayward, Ph.D. (not inventor) and Till Rohrich, Ph.D. (not inventor) submitted December 16, 2003 under 37 CFR 1.132, are acknowledged and will be further discussed below.

Applicant's amendment canceling claims 32-43, filed December 16, 2003 with respect to the rejection of claims 32-43 made under 35 U.S.C. 112 first paragraph for lack of scope of enablement of the recitation "an acid component" and "an alkaline effervescing component", and "an anti-ulcer agent" of record stated in the Office Action dated June 18, 2003 has been fully considered and is found persuasive to remove the rejection. Therefore, the said rejection is withdrawn.

Applicant's amendment canceling claims 32-43, filed December 16, 2003 with respect to the rejection of claims 32-43 made under 35 U.S.C. 112 second paragraph for omitting essential element, of record stated in the Office Action dated June 18, 2003 has been fully considered and is found persuasive to remove the rejection. Therefore, the said rejection is withdrawn.

Applicant's amendment canceling claims 32-35, filed December 16, 2003 with respect to the rejection of claims 32-35 under 35 U.S.C. 102(b) as being anticipated by Katdare et al. (5,853,759) for reasons of record stated in the Office Action dated June 18, 2003 has been considered and found persuasive to remove this particular rejection. Therefore, the said rejection is withdrawn.

Applicant's amendment canceling claims 32-39, filed December 16, 2003 with respect to the rejection of claims 32-39 under 35 U.S.C. 102(b) as being anticipated by Daifotis et al. (5,994,329) for reasons of record stated in the Office Action dated June 18, 2003 has been considered and found persuasive to remove this particular rejection. Therefore, the said rejection is withdrawn.

Applicant's amendment canceling claims 40-43, filed December 16, 2003 with respect to the rejection of claims 40-43 made under 35 U.S.C. 103(a) as being unpatentable over Katdare et al. (5,853,759) and Daifotis et al. (5,994,329) in view of Samejima et al. (4,462,982) for reasons of record stated in the Office Action dated June

18, 2003 has been considered and found persuasive to remove this particular rejection. Therefore, the said rejection is withdrawn.

The following is new rejection(s) necessitated by Applicant's amendment filed on December 16, 2003, wherein all original claims are cancelled and new claims have been submitted.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment submitted December 16, 2003 with respect to the new claims has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for "an acid component selected from the group consisting of citric acid, tartaric acid and alkali metal salts thereof". The original specification merely discloses "consisting of citric acid, tartaric acid, malic acid, fumaric acid, adipic acid, succinic acid, acid anhydrides, acid

salts, mixtures of acid salts', acid salts of disodium dihydrogen pyrophosphate, acid citrate salts and other related organic acids and their salts, and combinations thereof. Preferably, the acid component is citric acid (e.g., citric acid anhydrous) or tartaric acid." (see page 7 lines 1-5). Hence, the salts of disodium dihydrogen pyrophosphate are mere one particular alkali metal salts, a single particular specie of a genus alkali metal salts. Thus, a genus alkali metal salts encompassing each and every alkali metal in the new claims are not supported by a single particular specie of a genus, sodium salts.

Thus, the specification as originally filed does not provide support the method of treatment employing an acid component, alkali metal salts thereof.

Moreover, one skilled in the relevant art would recognize that alkali metal salts of citric acid, tartaric acid, malic acid, fumaric acid, adipic acid, succinic acid would not be an acid component upon hydrolysis, but rather a basic component in an aqueous solution.

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

### ***Claim Objection***

Claims 49-50 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the base claim 44 down to composition "consisting essentially of" recited ingredients. The composition of the base claim is actives recited

Art Unit: 1617

therein. However, the transitional phrase, "contains", employed in the dependent claim 49 is synonymous with "comprising", "including," or "characterized by," which is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997). See also MPEP 2111.03. The addition of further actives in dependent claims is **broader** than the scope of the base claim and therefore improper. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The dependent Claim 48 by reciting "about 5000 mg or more" without upper limit is **broader** than the scope of the base claim which recites 3.5 to about 6 grams with upper limit.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 44-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katdare et al. (5,853,759, of record).

Katdare et al. discloses that bisphosphonates including instant preferred bisphosphonates such as alendronate are known to have utility as pharmaceutical

Art Unit: 1617

agents for inhibiting bone resorption (see col.1 lines 14-42). Katdare et al. particularly discloses that a composition be administered orally comprising the instant preferred bisphosphonate, alendronate, is known to be useful in a method of treating osteoporosis in postmenopausal women (human mammals) (see col.1 lines 43-49). The disclosed pharmaceutical effervescent formulations of alendronate therein in tablet and powders which are placed in an convenient amount of water to produce effervescent liquid (solution), and that the patient drinks the effervescent solution, are for eliminating or minimizing side effects during the medication (i.e., for treating osteoporosis and/or inhibiting bone resorption in a mammal) (see col.1 lines 8-11 and 48-57, col.2 lines 63-67). The particular disclosed alendronate effervescent compositions of Katdare et al. in Example 1-4 comprises alendronate in an effective amount (known for treating osteoporosis and/or inhibiting bone resorption), the instant preferred acid component, citric acid, and the instant preferred alkaline effervescing component, sodium bicarbonate and sodium carbonate, flavoring agent or sweetener and color agent, and then an convenient amount of water added to produce effervescent solution to be administered orally (see Example 1 at col.4 line 34-35 and 46-56 in particular), and the composition also comprises a lubricant such as sodium benzonate and polyethylene glycol (PEG) (also known as a solubilizing agent) (see col.2 lines 24-26 and col.4 lines 21-33).

Note that the total weight of the solid composition of Katdare et al. in claims 4-5 therein is 3.365 g, very close to 3.5 g as instantly claimed (see claims 4-5, adding up the weight of all solid ingredients); Moreover, the total weight of the table is known to



range from about 100 to about 50,000 mg, about 1500-32500 mg, or about 20,800-30,150 mg (see col.3 lines 1-5).

The weight percentage of the acid component in Example 1 is 58.7% (which is calculated by 650 mg of citric acid per 1106.5 mg of total weight, see Example 1 at col.4), within the instant claimed range; the weight percentage of the alkaline component in Example 1 is 36.8% (which is calculated by 367+40 mg of sodium bicarbonate and sodium carbonate, per 1106.5 mg of total weight, see Example 1 at col.4), within the instant claimed range. The amount of bisphosphonate such as alendronate in the prior art composition ranges from 1 to 80 mg, overlapping with the instant claim.

Regarding the inherent property, the pH of the solution, it is noted that citric acid is employed in an excess in the composition therein to efficiently generate the effervescence and to sequester any ions to complex with alendronate, and to enhance favor as well, disclosed by Katdare et al. (see col.3 lines 60-65). Thus, the solution therein is acidic. The pKa of citric acid (known to used as a buffer),  $pK_1$ ,  $K_2$ ,  $K_3$  are 3.128, 4.761, and 6.396, respectively (provided by Bull "An Introduction to Physical Biochemistry" page 103, PTO-892). Thus, one of ordinary skill in the art would clearly recognize that the pH values in citric acid buffered solutions would be within the instantly claimed range about 4.5 to about 5.5, as shown in the calculation below:

Example I discloses that citric acid is 650 mg and the molecular weight (or formula weight, FW) of citric acid is 192.12 (provided by Aldrich Handbook page 436, PTO-892). Thus, the moles of citric acid is  $650 \div 192.12 = 3.38$  mmol.

Art Unit: 1617

Example I discloses that sodium bicarbonate is 367 mg and the molecular weight of sodium bicarbonate is 84.01 (provided by Aldrich Handbook page 1505, PTO-892).

Thus, the moles of sodium bicarbonate is  $367 \div 84.01 = 4.37$  mmol.

Example I discloses that sodium carbonate is 40 mg and the molecular weight of sodium carbonate is 105.99 (provided Aldrich Handbook page 1498, PTO-892). Thus, the moles of sodium carbonate is  $40 \div 105.99 = 0.38$  mmol.

It is known in the basic chemistry that the mole ratio of citric acid to sodium carbonate for neutralizing citric acid by sodium carbonate (or known as equal equivalent) is 2:3 (see col.3 line 67 to col.4 line 1) and the mole ratio of citric acid to sodium bicarbonate for neutralizing citric acid by sodium bicarbonate is 1:3.

Thus, 4.37 mmol of sodium bicarbonate neutralizes  $4.37 \times 1/3 = 1.46$  mmol of citric acid;

2.65 mmol of sodium carbonate neutralizes  $0.38 \times 2/3 = 0.25$  mmol of citric acid;

Therefore, the left or excess of citric acid in the solution

$$= 3.38 - (1.46 + 0.25) = 1.67 \text{ mmol.}$$

Therefore, 1.67 mmol, about a half amount of citric acid is free and left in the solution. Thus, the solution is acidic. As discussed above, according the known pKa values of citric acid, the pH value of the effervescent composition of Example 1 could be within the instant claim.

Moreover, after administering of the effervescent solution of Katdare et al., the pH of the mammal's stomach would be inherently raised to the range here since the

citric acid solution is a known buffered solution which would mediate the pH in the mammal's stomach for a period of time.

Thus, oral administration of Kuznicki's effervescent composition to a mammal is useful in methods of treating osteoporosis and inhibiting bone resorption.

Katdare et al. does not expressly disclose that the total weigh of the solid compositions of the prior art is 3.5 to about 6 grams such as 5000 mg (or 5 grams). Katdare et al. does not expressly disclose that the acid component is about 45% by weight of solid compositions of the prior art.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to determine or optimize the total weigh of the solid compositions of the prior art to 3.5 to about 6 grams such as 5000 mg (or 5 grams), and the acid component to about 45% by weight of solid compositions.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine or optimize the total weigh of the solid compositions of the prior art to 3.5 to about 6 grams such as 5000 mg (or 5 grams), since the claimed range 3.5 to about 6 grams lies inside ranges disclosed by the prior art, about 100 to about 50,000 mg, about 1500-32500 mg, or about 20,800-30,150 mg. Thus, a *prima facie* case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See also MPEP 2144.05.

Additionally, one having ordinary skill in the art at the time the invention was made would have been motivated to adjust the acid component to about 45% by weight

of solid compositions since the determination or optimization of amounts of a known acid compound to be used to adjust the known pH of the buffering composition based on the prior art teachings, is considered well within conventional skills in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 44-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daifotis et al. (5,994,329, of record).

Daifotis et al. discloses the compositions of a bisphosphonate comprising a bisphosphonate including instant preferred bisphosphonates such as alendronate, in oral forms therein such as in effervescent compositions, and also comprising solubilizing agents such as polyvinylpyrrolidone, coloring agents, and sweeteners (see

Art Unit: 1617

col.1 lines 15-58, col.11 line 55 to col.12 lines 3, col.12 lines 3-34), especially the liquid formulation or composition of Example 8 employed in the methods of treatments herein in Examples 2-6 comprising alendronate salt in the amounts within the instant claim (see col.5 lines 44-45, Example 8 at col.19), the instant preferred acid component, citric acid, and the alkaline component such as sodium citrate, and sodium hydroxide which is used to adjust the pH of the solution formulation to 6.75 (reads on the instant claim, about 6.5)(see particular Example 8 at col. 19 lines 40-62,). These compositions of a bisphosphonate be administered orally are useful for methods of treating osteoporosis and bone resorption in human mammals such as postmenopausal women (see also abstract, col.5 lines 21-23 and 29-35, col.7 lines 31-37, and Examples 2-6 at col.17-18).

Daifotis et al. further discloses that the methods and bisphosphonate compositions therein also comprise a histamine H2 receptor blocker (H2-antagonists), e.g., cimetidine, famotidin, and nizatidine, which are the instant preferred anti-ulcer agents, in order to minimize adverse gastrointestinal effects produced by a bisphosphonate (see col.13 lines 21-46).

Daifotis et al. does not expressly disclose that the total weigh of the solid compositions of the prior art is 3.5 to about 6 grams such as 5000 mg (or 5 grams). Daifotis et al. does not expressly disclose that the acid component is about 45% by weight of solid compositions of the prior art. Daifotis et al. does not expressly disclose the pH range claimed herein.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to determine or optimize the total weigh of the solid compositions of

Art Unit: 1617

the prior art to 3.5 to about 6 grams such as 5000 mg (or 5 grams), and the acid component to about 45% by weight of solid compositions.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine or optimize the total weight of the solid compositions of the prior art to 3.5 to about 6 grams such as 5000 mg (or 5 grams), since determining or optimizing the known amounts of bisphosphonate, solubilizing agents such as polyvinylpyrrolidone, coloring agents, and sweeteners in a pharmaceutical composition, and the determination or optimization of amounts of a known acid compound to be used to adjust the known pH of the buffering composition based on the prior art teachings, are considered well within conventional skills in pharmaceutical science, involving merely routine skill in the art. .

Moreover, after administering of the liquid composition of Example 8 in Daifotis et al., the pH of the mammal's stomach would be inherently raised to about the claimed range since the citric acid solution is a known buffered solution which would mediate the pH in the mammal's stomach for a period of time.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

***Response to Argument***

Applicant's arguments and the declarations of Marshall A. Hayward, Ph.D. (not inventor) and Till Rohrich, Ph.D., submitted December 16, 2003 under 37 CFR 1.132 have been fully considered but are ineffective to overcome the 103(a) rejections herein as to nonobviousness or unexpected results for the method herein over the prior art, as further discussed below.

First Applicant asserts in the declarations of Marshall A. Hayward and Till Rohrich that the pH value herein, 4.5 to about 5.5, is critical because the pH helps the stomach to rapidly eject the effervescent solution, but absent any supporting data for this conclusion. Thus, the declaration merely presents statements or conclusion, but fails to set forth any factual evidences. Note that Daifotis et al. (5,994,329) have provided factual evidences that their bisphosphonate compositions with the pH therein, e.g., 6.75, are capable of minimizing the potential for adverse gastrointestinal effects (see 5,994,329, Figures 1-8, Examples 1-8 and col.1 lines 15-16, col.4 45-46). Therefore, the declaration of Hayward is insufficient to rebut the prima facie case herein.

Second, Applicant asserts the claimed bisphosphonate composition having the pH value herein, 4.5 to about 5.5, by showing that the pH values of Example 2-5 of the specification at page 15-17, are 5.7, 5.7, 5.4 and 5.5. However, the instant claims are not limited to these particular compositions in Example 2-5 with particular amounts of each ingredient, especially the specific amounts of the acid and basic components which affect and determine the pH values of the compositions. Thus, the evidence in the

examples is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the amounts of the ingredients such as the acid and basic components in the claimed composition. See MPEP § 716.02(d).

Therefore, the evidence presented in specification herein is not seen to be clear and convincing in support the nonobviousness of the instant claimed invention over the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

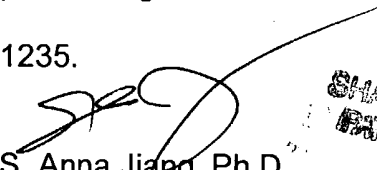


In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

  
S. Anna Jiang, Ph.D.  
Patent Examiner, AU 1617  
April 26, 2004

SHAOJIA ANNA JIANG  
PATENT EXAMINER